REMARKS

The Office action dated February 3, 2010 is acknowledged. Claims 1-90 are pending in the instant application. According to the Office action, claims 1-6, 11-23, 42-46 and 83-90 are rejected and claims 7-10, 24-41 and 47-82 have been withdrawn.

By the present response, claims 1 and 6 have been amended. Claim 1 has been amended to replace the term "substantially free from water" with "water content less than 5%-wt." Support for the amendment to claim 1 can be found throughout the present specification, such as at paragraph [0042]. Claim 6 has been amended to incorporate the feature that at least one of the gas-forming comonents is present in a micro-encapsulated form. Support for the amendment to claim 6 can be found throughout the present specification, such as at paragraph [0048]. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 6, 11-19, 42-46, 87, 89 and 90 under 35 U.S.C. 102(b)

Claims 6, 11-19, 42-46, 87, 89 and 90 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Publication No. 2001/0006677 (McGinity, et al.). The Examiner has reinstated this rejection from the Office action dated November 14, 2008 which argued that McGinity, et al. teach each and every limitation of the aforementioned claims. In particular, the Examiner stated that McGinity, et al. disclose effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration. The formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes, that the films may

be single layer or multilayer films and that the films comprise a water soluble or swellable film binder and active ingredient, a plasticizer and an effervescent couple which produces a gas (i.e., carbon dioxide or oxygen) when in water. The Examiner further stated that the effervescent components include sodium bicarbonate and sodium carbonate and acids such as citric acid and maleic acid. Still further, the Examiner stated that the film will dissolve/disintegrate at a controlled rate when exposed to a water containing solution and that the thickness of the film ranges from 0.1 mm to 2 mm. As a single layer, the Examiner concludes that the film will be the product of a single extrusion and when multi-layered film is involved, the different layer can be co-extruded in an extruder equipped with two die slots and then laminated together. Alternatively, the Examiner concluded that the different layers can be separately extruded one on the other. Regarding flavorings, the Examiner stated that those may include peppermint oil which comprises menthol and that the components are mixed together encompassing suspending the components in a suspending agent.

Regarding the process of the presently claimed invention, the Examiner concluded that in the case of a single layer, when the hot melt forms a film, the surface it extruded upon becomes dry and in the case of the two layers, the first layer which the second layer is extruded upon may be considered the substrate and becomes dry when the two layers form a film.

In the present Office action, the Examiner states that McGinity, et al. teach an alkaline agent and an acid, which meets the limitation of at least two or more gas forming components. The Examiner further argues that the granules may be in the state of a

powder or fine particles to increase the dissolution rate and that the granules are then placed into a mixer or hopper and mixed until thoroughly blended to form an effervescent mixture. It is also argued that the resulting mixture will have its components thoroughly dispersed throughout the film which encompasses the components being homogenously distributed within the preparation. It is also argued that the binders include acacia, tragacanth, gelatin, starch, cellulose materials such as methyl cellulose and sodium carboxymethyl cellulose, alginic acids and salts thereof, polyglycol, guar gum, polysaccharide, sugars, invert sugars, poloxamer, collagen, albumin, gelatin, cellulosics in non-aqueous solvents and combinations of the above and the like. The Examiner also states that other binders include, for example, polypropylene glycol, polyoxyethylene-polypropylene copolymer, polyethylene ester, polyethylene sorbitan ester, polyethylene oxide or combinations thereof and the like, thus encompassing the present claims.

Therefore, the Examiner concludes that McGinity, et al. disclose every limitation of the presently claimed invention.

The Applicant respectfully disagrees with the Examiner's assessment discussed above. It is respectfully submitted that McGinity, et al. fail to disclose each and every limitation of the claimed invention as presently amended.

As amended, claim 6 recites a preparation which is disintegratable in aqueous media and contains two or more gas-forming components wherein at least one of the gas-forming components is present in micro-encapsulated form. McGinity, et al. fail to teach the use of gas-forming components in micro-encapsulated form. Thus, McGinity, et al. fail to teach every limitation of independent claim 6 and so clearly the reference does not

anticipate the presently claimed invention.

Withdrawal of this rejection is respectfully requested.

Rejection of Claims 1-6, 11-23, 42-46 and 83-90 under 35 U.S.C. 103(a)

Claims 1-6, 11-23, 42-46 and 83-90 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2001/0006677 (McGinity, et al.) in view of U.S. Patent No. 6,177,096 (Zerbe, et al.). The Examiner also notes that U.S. Patent No. 4,833,179 (Young, et al.) teach that suspending agents to form suspensions include polyvinyl alcohol, poly-N-vinyl pyrrolidone, polyacrylic acid, polyacrylamide and hydroxyalkyl cellulose.

As previously argued by the Examiner, McGinity, et al. teach effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration and that the formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes. The Examiner continues on in the Final Office action to argue that the reference teaches every limitation of the presently claimed invention, except for the limitation that the coating compound composition is dried.

The Examiner in turn referred to Zerbe, et al. for teaching water soluble film for oral administration with instant wettability, and for teaching the missing limitations of McGinity, et al. except for the limitation of at least one or two gas forming agents. However, in this regard, the Examiner stated that when using a non-aqueous solvent in the process for making the compositions of McGinity, et al., it would have been obvious to have dried the film to remove the solvent with the motivation to form a dry film, as

disclosed by Zerbe, et al. The Examiner also concluded that it would have been obvious to use a non aqueous solvent to dissolve the components of the film composition, cast the films and dry them to make the compositions of McGinity, et al. motivated by the desire to avoid high temperatures that may degrade the effervescent components by using a method disclosed in the art that is used to make water dispersible films with a compatible solvent.

Regarding claims 84 and 88, the Examiner stated that it is generally *prima facie* obvious to select a known material for incorporation into a composition based on its recognized suitability for its intended use. Therefore, the Examiner concluded that it would have been obvious to one of ordinary skill in the art to have used an acrylate polymer in the composition of McGinity, et al. motivated by the desire to use a water-dispersible polyacrylate for its function as a binding agent in a water dispersible film.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. It is also well-established that the prior art cannot teach away from the claimed invention. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider McGinity, et al. fail alone, or in combination with the cited secondary reference, each and every limitation

of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered as the prior art teaches away.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Office action. The presently claimed invention is distinguishable from McGinity, et al. for at least the deficiency of McGinity, et al. discussed above. In addition, McGinity, et al. do not teach or disclose to dissolve or suspend water-soluble polymers and gas-forming components in a solvent. Still further, the McGinity, et al. reference fails to teach spreading a composition comprising both water-soluble polymers and gas-forming components and drying the composition.

McGinity, et al. teach a composition comprising both hot-melt extrudable water soluble or swellable effervescent film binders and an effervescent couple that are placed into a mixer and mixed until blended to form an effervescent mixture that is subsequently hot-melt extruded (paragraph [0094]). It is submitted, however, that the reason that a composition comprising a water soluble polymer and a gas-forming component is processed in a completely different manner according to the reference of McGinity, et al. is due to the fact that McGinity, et al. use a completely different technology, i.e., a hot-melt extrusion, to prepare effervescent controlled release water soluble films.

In contrast to the teachings of McGinity, et al., it is submitted that the process of the presently claimed invention recites the preparation of films using solvent-based technologies. It is further submitted that since the reference of McGinity, et al. is related to a completely different technology for preparing effervescent controlled release water

soluble films, the reference would not be referenced by one skilled in the art to arrive at the presently claimed invention. In particular, reference to McGinity, et al. by one skilled in the art regarding the present invention would render the presently claimed invention inoperable. This is particularly true since the disclosure of McGinity, et al. teaches away from the presently claimed invention in that McGinity, et al. teach that the process described therein does not require the use of solvents (emphasis added) (paragraph [0025]) in order to avoid disadvantages, such as longer exposure times of components to elevated temperatures. Thus, one skilled in the art would not refer to the teachings of McGinity, et al. and modify them by using a different technology, i.e., a solvent-based technology, since McGinity, et al. teaches away from the use of solvents.

Zerbe, et al. (and Young, et al.) fail to make up for any of the numerous deficiencies of McGinity, et al. and thus the combination of teachings of the references would not teach each and every limitation of the presently claimed invention.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in the McGinity, et al., alone or in combination with the cited secondary references. In addition, Zerbe, et al. and Young, et al. fail to make up for any of the missing limitations of McGinity, et al. Moreover, one skilled in the art would not be motivated to combine said references or to modify McGinity, et al. to arrive at the presently claimed invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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